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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,360	03/16/2001	Masato Horie	Q 63396	7873

7590

07/29/2002

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/29/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,360

Applicant(s)

HORIE ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20,22 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 20 and 23 have been amended and claims 19 and 21 have been cancelled as requested in the amendment of Paper No.9, filed on May 13, 2002. Claims 20, 22 and 23 are pending in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on May 13, 2002 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

5. Claims 20, 22 and 23 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in section 4 of Paper No.8. Briefly, the instant application has provided a description of an antibody to a protein encoded by an isolated DNA. However, the instant application does not disclose the biological role of this protein or its significance.

The Declaration of Masahito Horie under 37 CFR 1.132 filed May 13, 2002 is insufficient to overcome the rejection of claims 20 and 22-23 for the following reasons.

Applicant submits that “[t]he Declaration makes clear the function and biological significance of the LY6H protein or the expression product to which the antibody of the present invention binds. [...] The data indicate the important role of LY6H in synaptic transmission in the hippocampus and [...] the data indicate that the expression level of the LY6H protein in Alzheimer’s patients (n=11) is reduced. As demonstrated by the data, the LY6H protein can be used as a diagnostic marker for Alzheimer’s disease” (page 3, second and third paragraph of the Response). This has not been found persuasive for the following reasons.

The instant claims are drawn to antibodies, which bind specifically to a protein encoded by a newly isolated LY6H gene. According to the results of Experiment 1 presented in the Declaration of Masahito Horie, long-term potentiation (LTP) was significantly reduced in LY6H-knockout mice compared with the control. “This indicates that the loss of LY6H expression impairs synaptic transmission in the hippocampus” (page 2, last paragraph of the Declaration). However, the results do not reveal the specific role that LY6H protein plays in synaptic transmission. There is no evidence provided that would implicate LY6H protein in a specific material element of synaptic transmission, which would lead to a conclusion about a specific, credible and substantial role of LY6H gene. Based on the results presented in the Declaration, one skilled in the art would not make a reasonable assumption that addition of LY6H protein to the system lacking the LY6H gene (for example, administration of LY6H protein to LY6H-knockout mice) would eliminate the synaptic impairment. Similarly, the data presented in the Declaration about the decreased level of LY6H protein in the amygdala of post-mortem brains of AD patients (page 3, last paragraph of the Declaration) fail to provide any evidence or sound scientific reasoning that the LY6H protein can be used as a marker for AD.

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First, there is little doubt that many proteins are expressed abnormally during the development of such complicated multisymptom disease as Alzheimer's. Second, the current data only describes that LY6H protein levels in known AD tissue samples were lower compare to control known non-AD group. There are no results provided that would use the claimed antibodies to stain the unknown tissue samples and reveal the diagnosis of AD, which would be using the antibodies as a marker for AD.

Thus, in the absence of knowledge of biological significance of the LY6H protein there is no immediately obvious patentable use for the antibodies to the novel protein.

Claim Rejections - 35 USC § 112

6. Claims 20, 22 and 23 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

New grounds of rejection

7. Claims 20, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because of the presence of the term "comprising an amino acid sequence of SEQ ID NO:1" (claim 20) or ""comprising the nucleic acid sequence of SEQ ID NO:2 [or SEQ ID NO:3]" (claims 22 and 23) these claims encompass an antibody which binds to an epitope that is not contained within SEQ ID NO:1. It is old and well known in the art that the portion of a

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protein to which an antibody binds usually consists of no more than six to eight amino acid residues. It is also well known in the art long before the instant invention was made to express a recombinant protein as part of a fusion protein “comprising”, in addition to the amino acid sequence of a desired protein, an antigenic tail such as a “FLAG epitope”, a polyhistidine tail, or a “Protein A” fragment to facilitate the purification of the desired protein. Because of the presence of the term “comprising” in the instant claims, they encompass any antibody, which can bind to any epitope which can be expressed as a portion of a polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:1 and, therefore, they essentially encompass any antibody, which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody, which binds to any epitope other than an epitope, which is contained within SEQ ID NO:1 of the instant specification.

8. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 23 are vague and indefinite for reciting “an expression product expressed by a host cell”. It is obvious that a host cell, which comprises an expression vector comprising a specific nucleotide sequence, expresses other expression products as well. Therefore, it is not clear, which particular expression product is intended by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hopp et al. U.S. Patent 5,011,912 (04.30.1991).

As explained earlier, because claims 20, 22 and 23 encompass an antibody, which binds to any antigenic peptide, including the flag epitope DYKDDDDK, which was bound by the antibody of Hopp et al. prior to the time of the instant invention. Antibody of Hopp et al. is quoted here as an example of numerous antibodies that are encompassed by claims 20, 22 and 23.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
July 24, 2002

OC



JOHN ULM
PRIMARY EXAMINER
GROUP 1800